

EPA Jacket
83100-57
Vol. 1

PROCESSING REQUEST

Reg # 83100-57

Decision # 553433

Description:

Add producers to Basic CSF

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated:

07/17/2019 - Basic CSF

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Francisco Llarena-Arias

Division: RD

Phone: 703-347-0459

Date: 08/26/2019



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 24, 2019

JULIE KOZLOWSKI
AGENT
WAGNER REGULATORY ASSOCIATES, INC.
ROTAM AGROCHEMICAL COMPANY LTD.
P.O. BOX 640, 7217 LANCASTER PIKE, SUITE a
HOCKESSIN, DE 19707

Subject: CSF Notification per PRN 98-10 – Add producers to basic CSF
Product Name: Mesotrione 31.25% + Rimsulfuron 7.5% WG
EPA Registration Number: 83100-57
Application Date: 07-17-2019
Decision Number: 553433

Dear Ms. Kozlowski:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/17/2019

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Francisco Llarena-Arias at 703-347-0459 or by email at llarena-arias.francisco@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Erik Kraft".

Erik Kraft, Product Manager 24
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 26, 2019

JULIE KOZLOWSKI
AGENT
WAGNER REGULATORY ASSOCIATES, INC.
ROTAM AGROCHEMICAL COMPANY LTD.
P.O. BOX 640, 7217 LANCASTER PIKE, SUITE A
HOCKESSIN, DE 19707

Subject: CSF Notification per PRN 98-10 – Add producers to basic CSF
Product Name: Mesotrione 31.25% + Rimsulfuron 7.5% ✓ 6
EPA Registration Number: 83100-57
Application Date: 07-17-2019
Decision Number: 553433

Dear Ms. Kozlowski:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/17/2019

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Francisco Llarena-Arias at 703-347-0459 or by email at llarena-arias.francisco@epa.gov.

Sincerely,

Erik Kraft, Product Manager 24
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Decision Seq: 553433

Action Code: 332,NOTIFICATION,30

... ?

FFS Start Date:

Tentative Ind: No

Start/Stop Clock

FQPA Clock:

Due Date: 18-Aug-2019

75-Day Due Date:

Days Elapsed:

OPP Target Due Date:

21-Day Due Date:

FFS Original Decision:

Negotiated Due Date:

45/90 Due Date:

Registrant



Predeliberation

Add to Bundle?

Response Due Date:

Due Date:

Current Status: PENDING (24-Jul-2019)

Bundle ID:

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Bundle

75 Day Letters 45/90 Day Screen Primary Decisions Decision Milestone

FFS Negotiated Due Dates

OPP Target Due Date

Decision Comments

Payment

Unmatched Payments

Decision Ownership

Receipts

Data Package

Reduced Risk

Meetings & Milestones

FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S-1037583	Blarino-Ariza, Francisco	... 83100-57	18-Aug-2019	PENDING

Add additional producer to basic CSF

Viewing Record 1 of 1

Receipt for Section 3

S: 1037593

Milestone Email: julie@wagnerreg.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Enter More Information

Company: 83100 ROTAM AGROCHEMICAL COMPANY, LTD.

V

Tracking

Risk Manager: Registration Division, Risk Management Team 24

Product #: 83100-57

Product Name: Mesotrione 31.25% + Rimsulfuron 7.5% WG

Overridden:

Me Too Section3: 352-837

Me Too Product Name: DUPONT REALM Q HERBICIDE

...

Application Date: 17-Jul-2019



OPP Rec'd Date: 17-Jul-2019



Front End Date: 18-Jul-2019



Risk Manager Send Date: 18-Jul-2019



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ eCSF Ind: ☐ SmartLabel Ind: ☐ New Ingredient: ☐

Receipt Description:

Portal submission pkg #41109 Notification to add an additional producer to the basic CSF per PRN 98-10

Receipt Content | De
CSF
< >

View/Edit

New Ingredient
Request Date:

New Ingredient
Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

DOCUMENTUM

Submitted Electronically via CDX Portal

July 17, 2019

Document Processing Desk (NOTIF)
ATTN: Erik Kraft (PM 24)
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202



Subject: Mesotrione 31.25% + Rimsulfuron 7.5% WG (EPA Reg. No. 83100-57)
Notification to add additional producers to the Confidential Statement of Formula

Dear Mr. Kraft:

Wagner Regulatory Associates, Inc., as an agent for Rotam Agrochemical Company, Ltd. (EPA Company Number 83100), submits the enclosed notification to add an additional producer to the basic CSF.

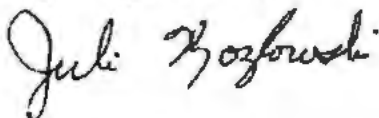
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

In support of this request, enclosed are the following documents:

- Letter from Rotam Agrochemical Company, Ltd., appointing WRA, Inc. as its agent
- Application for Pesticide Notification (Form 8570-1)
- Confidential Statement of Formula (Form 8570-4) – Basic
- Formulator's Exemption Statement (Form 8570-27)

If you have any questions about this submission, please do not hesitate to contact me at (302) 635-7279 or Julie@wagnerreg.com.

Respectfully submitted,



Julie Kozlowski
Agent for Rotam Agrochemical Company, Ltd.

Enclosures

DOCUMENTUM



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83100-57	2. EPA Product Manager Erik Kraft	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Agrochemical Co. Ltd. / Mesotrione 31.25% + Rimsulfuron 7.5% WG	PM# 24	
5. Name and Address of Applicant (Include Zip Code) Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:

Section - II

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification to add an additional producer to the basic CSF. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
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3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 20 oz.; 80 oz.; 20 oz. x12; 80 oz. x12	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
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6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other ___ adhesive backed label _____
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Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Julie Kozlowski	Title Agent for Rotam Agrochemical Company Ltd.	Telephone No. (Include Area Code) (302) 635-7279 (Julie@wagnerreg.com)
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Certification
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent for Rotam Agrochemical Company Ltd.
4. Typed Name Julie Kozlowski	5. Date July 17, 2019

6. Date Application Received

(Stamped)

DOCUMENTUM

 <div style="text-align: center;"> <p>United States Environmental Protection Agency Washington, DC 20460</p> <p>Formulator's Exemption Statement (40 CFR 152.85)</p> </div>		
<p>Applicant's Name and Address</p> <p>Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707</p>	<p>EPA File Symbol/Registration Number 83100-57</p> <hr/> <p>Product Name Mesotrione 31.25% + Rimsulfuron 7.5% WG</p> <hr/> <p>Date of Confidential Statement of Formula (EPA Form 8570-4) 07/17/2019</p>	
<p>As an authorized representative of the applicant for registration of the product identified above, I certify that:</p> <p>(1) This product contains the following active ingredient(s):</p> <p style="margin-left: 40px;">Mesotrione + Rimsulfuron</p> <p>(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).</p> <p>(3) Indicate by checking (A) or (B) below which paragraph applies:</p> <p><input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.</p> <p>(4) The following active ingredients in this product qualify for the formulator's exemption.</p>		
Source		
<p>Active Ingredient</p> <p>Mesotrione Rimsulfuron</p>	<p>Product Name</p> <p>████████████████████ ████████████████████</p>	<p>Registration Number</p> <p>██████████ ██████████</p>
<p>Signature</p> <p><i>Julie Kozlowski</i></p>	<p>Name and Title</p> <p>Julie Kozlowski, Agent for Rotam</p>	<p>Date</p> <p>07/17/2019</p>

PROCESSING REQUEST

Reg # 83100-57

Decision # 538387

Description: CSFs

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated:

2/08/2018

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: E Thornton

Division: RD

Phone: 305-6799

Date: 3/19/2018



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 19, 2018

Ms. Keeva Shultz
Agent
Rotam Agrochemical Co., Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike
Suite A
Hockessin, DE 19707

Subject: CSF Notification per PRN 98-10 – Adding additional producers to the basic CSF
Product Name: **Mesotrione 31.25% + Rimsulfuron 7.5% WG**
EPA Registration Number: 83100-57
Application Date: February 8, 2018
Decision Number: 538387

Dear Ms. Shultz:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/08/2018

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Eleanor Thornton at 703-305-6799 or by email at Thornton.eleanor@epa.gov.

Sincerely,

Erik Kraft, Product Manager 24
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Submitted Electronically via CDX Portal

February 8, 2018

Document Processing Desk (NOTIF)
ATTN: Erik Kraft (PM 24)
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202



**Subject: Mesotrione 31.25% + Rimsulfuron 7.5% WG – EPA Reg. No. 83100-57
Notification to add additional producers to the Confidential Statement of Formula**

Dear Mr. Kraft,

Wagner Regulatory Associates, Inc., as agent for Rotam Agrochemical Co., Ltd., is submitting a notification to add additional producers to the basic CSF.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

In support of this request, the following documents and studies are being submitted electronically via the EPA CDX PSP portal:

- Letter from Rotam Agrochemical Co., Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Notification (8570-1)
- Confidential Statement of Formula (8570-4) - Basic
- Formulators Exemption (8570-27)

Thank you in advance for your efforts in reviewing this submission. Please do not hesitate to contact me by email at keeva@wagnerreg.com or by phone at 302-635-7281 should you have any questions.

Respectfully submitted,

Keeva Shultz

Keeva Shultz
Agent for Rotam Agrochemical Co., Ltd.

Enclosures

DOCUMENTUM



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83100-57	2. EPA Product Manager Erik Kraft	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Agrochemical Co. Ltd. / Mesotrione 31.25% + Rimsulfuron 7.5% WG	PM# 24	
5. Name and Address of Applicant (Include Zip Code) Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:

Section - II

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification to add additional producers to the basic CSF. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
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3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 20 oz.; 80 oz.; 20 oz. x12; 80 oz. x12	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
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6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other ___ adhesive backed label _____
--	--

Section - IV**1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)**

Name Keeva Shultz	Title Agent for Rotam Agrochemical Company Ltd.	Telephone No. (Include Area Code) (302) 635-7281 (keeava@wagnerreg.com)
----------------------	--	--

Certification
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title
 Agent for Rotam Agrochemical Company Ltd.

4. Typed Name
 Keeva Shultz

5. Date
 February 8, 2018

6. Date Application Received
 (Stamped)



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707	EPA File Symbol/Registration Number 83100-57
	Product Name Mesotrione 31.25% + Rimsulfuron 7.5% WG
	Date of Confidential Statement of Formula (EPA Form 8570-4) 02/08/2018

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Mesotrione + Rimsulfuron

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Mesotrione	[REDACTED]	[REDACTED]
Rimsulfuron	[REDACTED]	[REDACTED]
DOCUMENTUM		
Signature	Name and Title	Date
	Keeva Shultz, Agent	02/08/2018

PROCESSING REQUEST

Reg # 83100-57

Decision # 52923 3

Description: Adding Basic CSF

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 5/5/17 (Basic)

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Lisa Rahel

Division: RD

Phone: 703-347-0459

Date: 11/15/17



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

83100-57

Date of Issuance:

11/15/17

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Mesotrione 31.25% + Rimsulfuron
7.5% WG

Name and Address of Registrant (include ZIP Code):

Anna Armstrong
Agent for Rotam Agrochemical Co., Ltd.
Rotam Agrochemical Co., Ltd.
c/o Wagner Regulatory Associates, Inc.
PO Box 640
Hockessin, DE 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Erik Kraft, Product Manager 24
Fungicide & Herbicide Branch, Registration Division (7505P)

Date:

11/15/17

2. You are required to comply with the data requirements described in the DCI identified below:

- a. Mesotrione GDCI-122990-1474

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 83100-57."
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/05/2017

If you have any questions, please contact Lisa Pahel by phone at (703) 347-0459, or via email at pahel.lisa@epa.gov.

Enclosure: Product chemistry review dated 11/06/2017, DP#440413; Acute Toxicology memorandum dated 10/26/2017, DP#440414

GROUP	27	2	HERBICIDES
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Mesotrione 31.25% + Rimsulfuron 7.5% WG

An Herbicide for Post-Emergence Use in Field Corn Grown for Grain or Silage

ACTIVE INGREDIENTS:

BY WT.

Mesotrione 31.25%

Rimsulfuron: N-((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)-3-(ethylsulfonyl)-2-pyridinesulfonamide 7.50%

OTHER INGREDIENTS: 61.25%

TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted detalle.
 (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal), call: 1-800-222-1222. For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC: 1-800-424-9300.	

[Optional referral statements when booklets and container labels are used:

See Panel for First Aid Instructions and booklet for complete Precautionary Statements and Directions for Use.

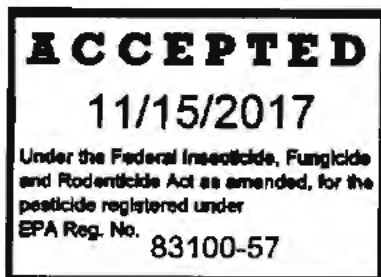
See label booklet for complete Precautionary Statements, Directions For Use, and Storage and Disposal.

See label booklet for additional Precautionary Statements, Directions For Use, and Storage and Disposal.

See label booklet for complete Directions For Use.]

Manufactured For:

Rotam Agrochemical Co. Ltd.
 26/F, E-Trade Plaza
 24 Lee Chung Street
 Chai Wan, Hong Kong



EPA Reg. No.: 83100-LT

EPA Est. No.:

Net Contents:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, made of butyl rubber ≥ 14 mils, natural rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, or nitrile rubber ≥ 14 mils
- Shoes plus socks
- Protective eyewear

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROL STATEMENTS

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR Part 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. If pesticide gets on skin, wash immediately with soap and water.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters or rinsate.

Surface Water Protection

This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of rimsulfuron from runoff water and sediment. Runoff of this product will be greatly reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated area. Protect the forage and habitat of non-target organisms by minimizing spray drift. For further guidance and instructions on how to minimize spray drift, refer to the Spray Drift Advisories section of this label.

WINDBLOWN SOIL PARTICLES: Mesotrione 31.25% + Rimsulfuron 7.5% WG has the potential to move off-site due to wind erosion. Soils that are subject to wind erosion usually have a high silt and/or fine to very fine sand fractions and low organic matter content. Other factors which can affect the movement of windblown soil include the intensity and direction of prevailing winds, vegetative cover, site slope, rainfall, and drainage patterns. Avoid applying Mesotrione 31.25% + Rimsulfuron 7.5% WG if prevailing local conditions may be expected to result in off-site movement.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

The following PPE is required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water:

- Coveralls
- Chemical-resistant gloves, made of butyl rubber ≥ 14 mils, natural rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, or nitrile rubber ≥ 14 mils
- Shoes plus socks

PRODUCT INFORMATION

Use **Mesotrione 31.25% + Rimsulfuron 7.5% WG** in accordance with instructions on this label.

Mesotrione 31.25% + Rimsulfuron 7.5% WG is for use as a post-emergence herbicide for selective burndown and residual control of listed annual grass and broadleaf weeds in field corn grown for grain or silage.

To improve residual or burndown control, **Mesotrione 31.25% + Rimsulfuron 7.5% WG** can be tank mixed with a variety of herbicides.

Mesotrione 31.25% + Rimsulfuron 7.5% WG works best when used in a planned sequential application herbicide program, following a pre-plant application of another labeled corn herbicide. Consult the label of the corn herbicide product for specific use directions and additional information.

For post-emergence application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**, if activating rainfall or sprinkler irrigation (greater than $\frac{1}{2}$ inch) is not received within 5 to 7 days following application, cultivate or follow with a sequential application of a nicosulfuron-containing product, or glyphosate, as necessary.

Mesotrione 31.25% + Rimsulfuron 7.5% WG is rainfast in 4 hours.

Use Restrictions

- Do not make application to field corn grown for seed, to popcorn, or to sweet corn.
- Do not make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** through any type of irrigation system.
- Do not apply **Mesotrione 31.25% + Rimsulfuron 7.5% WG** by aerial application unless noted otherwise under the specific crop section on the label.
- Do not make application of more than 4.0 oz. of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** per acre per year.
- Do not apply more than 1.0 oz. a.i. of rimsulfuron per year. This includes post-emergence applications of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**, as well as other products containing the active ingredient rimsulfuron.
- Do not make application of more than 3.85 oz. a.i. of mesotrione per year. This includes post-emergence applications of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**, as well as other products containing the active ingredient mesotrione. Do not apply the second treatment of a mesotrione-containing product within 14 days of the first treatment.
- Do not make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** to corn that shows symptoms of herbicide injury from prior applications made to the previous or current crop.
- Do not use liquid nitrogen fertilizer as the total carrier solution for post-emergence applications.
- Do not graze, feed forage, grain or fodder (stover) from treated areas to livestock within 45 days of a **Mesotrione 31.25% + Rimsulfuron 7.5% WG** treatment.
- Do not harvest grain within 70 days or harvest forage or stover within 45 days of a **Mesotrione 31.25% + Rimsulfuron 7.5% WG** treatment.
- **Mesotrione 31.25% + Rimsulfuron 7.5% WG** contains the safener isoxadifen-ethyl at 0.0375 lb. per pound of product. Applying the maximum application rate of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** at 4.0 oz. per acre will deliver 0.01 lb. of isoxadifen-ethyl per acre. When tank mixing for applications to field corn, do not make application of more than a total of 0.17 lb. of isoxadifen-ethyl per acre per year.
- It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture.
- Injury or loss of desirable trees or vegetation may occur from failure to observe the following:

- Do not make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** or drain or flush application equipment on or near desirable trees or other plants, or on areas where their roots may extend, or in locations where the chemical may be washed or moved into contact with their roots.
- Do not use on lawns, walks, driveways, tennis courts, or similar areas.
- Prevent drift or spray to desirable plants.
- Do not contaminate any body of water.
- Thoroughly clean application equipment immediately after use. (Refer to the **SPRAYER PREPARATION/CLEAN-UP** section of this label for instructions).

Use Precautions

- Crop injury may result following an application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** if there is a prolonged period of cold weather and/or in conjunction with wet soils.

Resistance

Mesotrione 31.25% + Rimsulfuron 7.5% WG contains two active ingredients with two different modes of action. Mesotrione is classified as a Group 27 herbicide and Rimsulfuron is classified as and a Group 2 herbicide. As a mixture herbicide, each listed weed may not be controlled by both mechanisms of action.

Herbicide resistance is defined as the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring or induced by such techniques as genetic engineering or selection of variants produced by tissue culture or mutagenesis. While the development of resistance is well understood, it is not easily predicted. Therefore, herbicides must be used in conjunction with resistance management strategies in the area. Consult the local or State agricultural advisors for details. If weed resistance develops in the area, this product used alone may not continue to provide sufficient levels of weed control. If the reduced levels of control cannot be attributed to improper application timing, unfavorable weather conditions or abnormally high weed pressure, a resistant strain may have developed.

To delay herbicide resistance, consider:

- Avoiding the consecutive use of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** or other target site of action Group 27 and Group 2 herbicides that have a similar target site of action, on the same weed species.
- Using tank mixtures or premixes with herbicides from different target site of action Groups as long as the involved products are all registered for the same use, have different sites of action, and are both effective at the tank mix or prepack rate on the weed(s) of concern.
- Basing herbicide use on a comprehensive Integrated Pest Management (IPM) program.
- Monitoring treated weed populations for loss of field efficacy.

Users should scout before and after application. Users should report lack of performance to registrant or their representative. Contact your local extension specialist, certified crop advisors, and/or manufacturer for herbicide resistance management and/or integrated weed management recommendations for specific crops and resistant weed biotypes.

Integrated Pest Management

Integrate **Mesotrione 31.25% + Rimsulfuron 7.5% WG** into an overall weed pest management strategy whenever the use of an herbicide is required. Practices known to reduce weed development (tillage, crop competition) and herbicide use (weed scouting, proper application timing, banding) should be followed wherever possible. Consult local agricultural and weed authorities for additional IPM strategies established for your area.

Environmental Conditions And Biological Activity

Mesotrione 31.25% + Rimsulfuron 7.5% WG rapidly inhibits the growth of susceptible weeds through absorption via the shoots and roots of plants. Rainfall or sprinkler irrigation is required to move **Mesotrione 31.25% + Rimsulfuron 7.5% WG** into the soil. Susceptible weeds will typically not emerge from post-emerge application with activating rainfall or sprinkler irrigation (>0.5 inch). Occasionally, susceptible weeds may germinate and emerge a few days after application, but growth ceases and leaves become chlorotic three to five days after emergence. Death of leaf tissue and growing point will follow in some species, while others will remain green but stunted and noncompetitive.

APPLICATION INFORMATION

Ground Applications

Use a minimum of 15 gallons of water per acre to ensure thorough coverage of the weeds and the best performance. Use a minimum of 10 gallons of water per acre for light, scattered stands of weeds.

Adjust the spray boom to the lowest possible spray height recommended in manufacturers' specifications for optimal product performance and minimal spray drift. Be sure that equipment is set up to avoid applying an excessive rate directly over the rows and into the corn plant whorl. Overlaps or starting, stopping, slowing, and turning while spraying may result in crop injury.

Aerial Applications

Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** may be made by air for pre-emergence or post-emergence weed control only in the following states: Alabama, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Tennessee, and Texas.

Applications must be made in a minimum of 2 gallons of water per acre. Use only nozzles producing coarse-ultra coarse droplets. Do not use nozzles producing fine-medium size droplets.

SPRAY DRIFT**Aerial Applications:**

- Do not release spray at a height greater than 10 ft. above the vegetative canopy, unless a greater application height is necessary for pilot safety.
- For applications prior to the emergence of crops and target weeds, applicators are required to use a Coarse or coarser droplet size (ASABE S572.1).
- For all other applications, applicators are required to use a Medium or coarser droplet size (ASABE S572.1).
- The boom length must not exceed 65% of the wingspan for airplanes or 75% of the rotor blade diameter for helicopters.
- Applicators must use ½ swath displacement upwind at the downwind edge of the field.
- Nozzles must be oriented so the spray is directed toward the back of the aircraft.
- Do not apply when wind speeds exceed 10 miles per hour at the application site.
- Do not apply during temperature inversions.

Ground Boom Applications:

- Apply with the nozzle height recommended by the manufacturer, but no more than 3 feet above the ground or crop canopy unless making a turf, pasture, or rangeland application, in which case applicators may apply with a nozzle height no more than 4 feet above the ground.
- For applications prior to the emergence of crops and target weeds, applicators are required to use a Coarse or coarser droplet size (ASABE S572.1).
- For all other applications, applicators are required to use a Medium or coarser droplet size (ASABE S572.1).
- Do not apply when wind speeds exceed 10 miles per hour at the application site.
- Do not apply during temperature inversions.

Boom-less Ground Applications:

- Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) for all applications.
- Do not apply when wind speeds exceed 10 miles per hour at the application site.
- Do not apply during temperature inversions.

SPRAY DRIFT ADVISORIES**SPRAY DRIFT****Boom-less Ground Applications:**

- Setting nozzles at the lowest effective height will help to reduce the potential for spray drift.

Handheld Technology Applications:

- Take precautions to minimize spray drift.

THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.

IMPORTANCE OF DROPLET SIZE

An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions.

Controlling Droplet Size – Ground Boom

- Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a

higher flow rate.

- **Pressure** - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size.
- **Spray Nozzle** - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.

Controlling Droplet Size – Aircraft

- **Adjust Nozzles** - Follow nozzle manufacturers recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight.

BOOM HEIGHT – Ground Boom

Use the lowest boom height that is compatible with the spray nozzles that will provide uniform coverage. For ground equipment, the boom should remain level with the crop and have minimal bounce.

RELEASE HEIGHT - Aircraft

Higher release heights increase the potential for spray drift. When applying aerially to crops, do not release spray at a height greater than 10 ft. above the crop canopy, unless a greater application height is necessary for pilot safety.

SHIELDED SPRAYERS

Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area.

TEMPERATURE AND HUMIDITY

When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.

TEMPERATURE INVERSIONS Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions.

WIND

Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.

Air Assisted (Air Blast) - Field Crop Sprayers

Air assisted field crop sprayers carry droplets to the target via a downward directed air stream. Some may reduce the potential for drift, but if a sprayer is unsuitable for the application and/or set up improperly, high drift potential can result. It is the responsibility of the applicator to determine that a sprayer is suitable for the intended application, is configured properly, and that drift is not occurring. **Note:** Air assisted field sprayers can affect product performance by affecting spray coverage and canopy penetration. Consult the application equipment section of this label to determine if use of an air assisted sprayer is recommended.

Drift Control Additives

Using product compatible drift control additives can reduce drift potential. When a drift control additive is used, read and carefully observe cautionary statements and all other information on the additive's label. If using an additive that increases viscosity, ensure that the nozzles and other application equipment will function properly with a viscous spray solution. Preferred drift control additives have been certified by the Chemical Producers and Distributors Association (CPDA).

SPRAY ADJUVANTS

Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** must include a crop oil concentrate (COC) or a high surfactant oil concentrate (HSOC) for control of emerged weeds.

The use of a nonionic surfactant (NIS) instead of a COC or HSOC is allowed, but the level of weed control achieved when using a COC or HSOC is consistently better than when using NIS. **The use of methylated seed oil (MSO) adjuvants, or MSO blend adjuvants may result in severe crop injury. MSO adjuvants are not recommended.** In addition to COC or HSOC, **23**

HSOC, always add spray grade UAN (e.g., 28-0-0) to the spray solution or AMS (except if precluded elsewhere on this label).

If application is made in tank mix combination with a glyphosate that contains a built-in adjuvant such as ABUNDIT® Extra, be sure that the total adjuvant load is equal to the directions on this label. Select adjuvants authorized for use with both products.

Do not use with additives that alter the pH of the spray solution below 5.0 or above 9.0 as rapid product degradation can result. Spray solutions of pH 6.0 - 8.0 allow for optimum stability of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**.

Ammonium Nitrogen Fertilizer

- Make application of 2 quarts/acre of a high-quality urea ammonium nitrate (UAN), such as 27%N or 32%N, or 2 pounds/acre of a spray-grade ammonium sulfate (AMS).

High Surfactant Oil Concentrate (HSOC)

- Make application at 0.5% (2 quarts per 100 gallons spray solution).

Nonionic Surfactant (NIS)

- Make application at 0.25% v/v (1 quart per 100 gallons spray solution).
- Surfactant must have at least 60% nonionic surfactant with a hydrophilic/lipophilic balance (HLB) that is greater than 12.
- For post-emergence applications, do not use liquid nitrogen fertilizer as the total carrier solution.

Petroleum Crop Oil Concentrate (COC)

- Make application at 1% v/v (1 gallon per 100 gallons spray solution) or 2% under dry conditions.
- Oil-based adjuvants must have at least 80% high quality, petroleum (mineral) oil with a minimum of 15% surfactant emulsifiers.

Special Adjuvant Types

- Adjuvant combination products may be used at doses that provide the required amount of NIS, COC, and/or ammonium nitrogen fertilizer. Consult the product literature for use rates and restrictions.

Tank Mix Compatibility Testing

Conduct a compatibility test before tank mixing to ensure physical compatibility of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** and other products. Use a clear quart-sized jar with lid, and mix the ingredients using their relative proportions. Invert the jar containing the mixture several times to mix the solution and observe for approximately 30 minutes. Do not use if the mixture balls-up, forms flakes, sludge, gel, oily film or layers, or other precipitates because these indicate that the products are not compatible.

TANK MIX INSTRUCTIONS

1. Fill the tank $\frac{1}{4}$ to $\frac{1}{2}$ with water.
2. While agitating, add the specified amount of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**. Maintain agitation until the product is fully dispersed (for at least 5 minutes).
3. Continue agitation and fill the remainder of the tank with water once the **Mesotrione 31.25% + Rimsulfuron 7.5% WG** is fully dispersed. Thoroughly mix **Mesotrione 31.25% + Rimsulfuron 7.5% WG** with water before adding any other material.
4. While the tank is filling with water, add the required spray adjuvants (crop oil concentrate, nonionic surfactant, or ammonium nitrogen fertilizer).
5. If tank is not continuously agitated, settling will occur. If settling occurs, thoroughly mix before applying.
6. To avoid product degradation, make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** spray mixture within 48 hours of mixing.

It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture. Do not use a tank mix partner product if its label conflicts with this label. Tank mixture directions are only for use in states where the tank mixture product and application site are registered. Certain states or geographical regions may have established dose rate limitations. Consult your state Pesticide Control Agency for additional information regarding the maximum use rates.

SPRAYER PREPARATION/CLEAN-UP

Spray equipment should be clean and free of previous pesticide deposits or residue before using **Mesotrione 31.25% + Rimsulfuron 7.5% WG** followed by proper cleaning after application. Before applying **Mesotrione 31.25% + Rimsulfuron 7.5% WG**, clean all application equipment, following the clean-up procedures specified on the label of the product previously sprayed. Use the procedure that follows, if no clean-up procedure is provided. Thoroughly clean all mixing

and spray equipment to avoid subsequent adverse crop response immediately after application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**.

Clean-up Procedure

1. Drain the spray tank and thoroughly hose down the inside surfaces. Flush the hoses, boom, and tank with clean water for at least 5 min.
2. Fill the tank partially with clean water. For every 100 gallons of water, add one gallon of household ammonia*** (that contains 3% active). Finish filling the tank with water, then flush the cleaning solution through the boom, hoses, and nozzles. Completely fill the tank with water and agitate/recirculate for at least 15 min. Again, flush the boom, hoses, and nozzles with the cleaning solution. Drain the tank.
3. Repeat Step 2.
4. Remove and clean the nozzles and screens separately in a container with the cleaning agent and water.
5. Rinse the tank with clean water thoroughly for a minimum of 5 minutes, flushing the water through the boom and hoses.

***Equivalent amounts of an alternate strength ammonia solution or a tank cleaner recommended by the equipment manufacturer may be used.

Notes:

- Read and follow product label directions for proper disposal of rinsate.
- To dislodge any visible pesticide deposits, steam-cleaning of aerial spray tanks should be conducted.
- When spraying or using mixing equipment over an extended period of time with **Mesotrione 31.25% + Rimsulfuron 7.5% WG**, partially fill the tank with fresh water at the end of each day of spraying, flush the boom and hoses, and allow to sit overnight.

Do not drain or flush spray equipment or rinsate on or near desirable trees or plants.

Do not contaminate any body of water including irrigation water that may be used on other crops.

If the sprayer has been stored or left idle, purge the spray boom and nozzles with clean water before starting any application.

If equipment is not cleaned properly, residue of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** can remain in spray equipment, and may be released during subsequent applications potentially causing adverse crop response to certain crops and other vegetation. Rotam accepts no liability for any effects due to equipment that is not cleaned properly.

SOIL INSECTICIDE INTERACTION INFORMATION

Mesotrione 31.25% + Rimsulfuron 7.5% WG may interact with certain insecticides previously applied to the crop. Crop response varies with field corn variety, insecticide used, insecticide application method, and soil type.

Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** may be made to corn previously treated with chlorethoxyfos; chlorethoxyfos/bifenthrin; cyfluthrin; or tefluthrin insecticides or other non-organophosphate (OP) soil insecticides regardless of soil type.

Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** may be made with pyrethroid type insecticides or with diamide type insecticides.

- Do not make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** within 45 days of crop emergence where an organophosphate insecticide was applied as a treatment since crop injury may result. Unacceptable crop injury may occur with applications made to corn previously treated with chlorpyrifos or other similar organophosphate insecticides. Any crop injury or yield loss resulting from these applications are the responsibility of the grower.
- Do not tank mix **Mesotrione 31.25% + Rimsulfuron 7.5% WG** with product containing bentazon or severe crop injury may result.
- Do not apply **Mesotrione 31.25% + Rimsulfuron 7.5% WG** in tank mix with foliar-applied organophosphate or carbamate insecticides such as chlorpyrifos, malathion, parathion, etc., as severe crop injury may result. To avoid crop injury or antagonism, make application of these products at least 7 days before or 7 days after the application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**.

ROTATIONAL CROPS

Rotational crops vary in their response to low concentrations of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** remaining in the soil. The amount of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** that may be present in the soil is dependent on soil moisture, soil temperature, application rate, elapsed time since application and other environmental factors. When **Mesotrione 31.25% + Rimsulfuron 7.5% WG** is used in combination with other products, always follow the most restrictive rotational crop requirements.

Planting unspecified rotational crops, or those rotational crops that are specified at shorter than listed intervals may result in injury to the rotational crop.

When using **Mesotrione 31.25% + Rimsulfuron 7.5% WG**, follow the rotational intervals listed below:

Crop Rotational Intervals – 4 Oz. Maximum Use Rate per Acre per Year (0.078 lbs. a.i. mesotrione and 0.019 lbs. a.i. rimsulfuron)

Crop	Crop Rotational Interval
Corn (field)	Anytime
Cereals, Winter (wheat)	4 Months
Cereals, Spring (barley, oats, wheat)	9 Months
Alfalfa*†, Canola*, Corn (pop, seed, or sweet), Cotton*, Flax, Peas ^{1,2} , Peanuts, Potatoes, Rice, Snap Beans ^{1,2} , Sorghum*, Soybeans, Sunflower, Sweet Potatoes/Yams**, Tobacco	10 Months
Cucurbits, Dry Beans, Red Clover, Sugar Beets	18 Months
Crops Not Listed	18 Months

*18 months in the Red River Valley region of ND and MN. In all other areas, the rotation intervals should be extended to 18 months if drought conditions persist following application and before the rotational crop is planted, unless sprinkler irrigation is used and totals greater than 15" during the growing season.

**On soils with pH 6.5 or less.

†On sprinkler irrigated fields in Idaho, Utah, and Northern Nevada it is best to use deep fall tillage such as plowing prior to planting alfalfa. Product degradation may be less on furrow irrigated soils and some crop injury may occur.

¹Plant these rotational crops only if the criteria below have been met. If all criteria are not met, plant peas and snap beans a minimum of 18 months after **Mesotrione 31.25% + Rimsulfuron 7.5% WG** application.

- A minimum of 20" of rainfall plus irrigation has been received between treatment and planting of the rotational crop.
- Soil pH is 6.0 or greater.
- Treatment of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** applied no later than June 30 the year preceding rotational crop planting.
- No other HPPD herbicides were applied the year before planting peas and snap beans.

²Do not plant peas or snap beans on sand, sandy loam or loamy sands in Minnesota or Wisconsin.

FIELD CORN GROWN FOR GRAIN OR SILAGE - Directions for Use

Post-Emergence

Make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** at 4 oz. per acre as a post-emergence broadcast treatment to corn up to 20" tall or that is exhibiting up to and including 6-leaf collars (V6), whichever is more restrictive.

While **Mesotrione 31.25% + Rimsulfuron 7.5% WG** has a wide application window, research has shown best results are obtained when treatments are made early post-emergence when corn and weeds are small. For best overall performance target post-applications to corn that is generally less than 12" tall. Treatment of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** made after weed emergence will provide contact control of labeled weeds as well as residual control of later emerging weeds.

Make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** when grasses and broadleaf weeds are young and actively growing, but before they exceed sizes listed on this label. Treatments made to weeds taller than those listed on this product label may result in incomplete control. Grass and broadleaf weed competition due to incomplete control may result in reduce corn yields.

Restrictions:

- Do not make application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** to corn that shows herbicide injury from previous applications made to the current or preceding crop.
- Do not apply more than one application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** per year.
- Do not make application of more than 4 oz. of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** per acre (0.078 lbs. a.i. mesotrione/acre and 0.019 lbs. a.i. rimsulfuron/acre) during a single year.

WEEDS CONTROLLED/SUPPRESSED

Weeds Controlled with a Post-Emergence Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**

Broadleaf & Grass Weeds	Mesotrione 31.25% + Rimsulfuron 7.5% WG Alone 4.0 Oz./Acre	Mesotrione 31.25% + Rimsulfuron 7.5% WG 4.0 Oz./Acre Plus Atrazine
	Weeds <5 Inches Tall	
Amaranth, Palmer ¹	S ³	C ³
Amaranth, Powell	C	C
Amaranth, spiny	C	C
AtripleX	C	C

Barnyardgrass	C	C
Bluegrass, annual	C ³	C
Broadleaf signalgrass	S ²	C ²
Buckwheat, wild	S	S
Buffalobur	C	C
Burcucumber	C ²	C
Carpetweed	C	C
Carrot, wild	C	C
Chickweed, common	C	C
Cocklebur, common	C	C
Dandelion	C	C
Dock, curly	S	S
Foxtails (bristly, giant, green, yellow)	C ⁴	C ⁴
Galinsoga	C	C
Hemp	C	C
Horsenettle	C	C
Itchgrass	C	C
Jimsonweed	C	C
Johnsongrass, seedling	S	C
Knotweed, prostrate	S	S
Kochia ¹	C ²	C ²
Lambsquarters, common	C	C
Mallow, Venice	C	C
Marestail (horseweed) ¹	S	C
Morningglogy (entireleaf, ivyleaf, pitted)	C ²	C ²
Mustard, wild	C	C
Nightshade (black, eastern black)	C	C
Nightshade, hairy	C	C
Nutsedge, yellow	S	S
Panicum (Texas, browntop)	C ³	C ³
Panicum, fall	C	C
Pigweed (redroot, smooth, tumble)	C	C
Pokeweed, common	S	S
Potatoes, volunteer	C	C
Pusley, Florida	C ²	C ²
Quackgrass	S	C
Ragweed, common	C ³	C ³
Ragweed, giant	C ³	C ³
Ryegrass ¹ (Italian, perennial)	S	C
Sandbur (field, longspine)	C ³	C ³
Sesbania, hemp	C	C
Shattercane	C ⁴	C ⁴
Sida, prickly (teaweed)	S ³	C ³
Smartweed (ladysthumb, pale, Pennsylvania)	C	C
Sorghum, album	C	C
Stinkgrass	S	C
Sunflower, common	C	C
Thistle, Canada	S	S
Timothy	C	C
Velvetleaf	C	C ³
Volunteer cereals	C	C
Waterhemp ¹	S ³	C ³
Wild oats	C	C
Wild proso millet	S ⁴	C ⁴

Wirestem muhly	C	C
Witchgrass	C	C
Woolly cupgrass	C ²	C ⁴
C = Control S = Suppression		
¹ ALS-resistant biotypes are known to exist.		
² Apply before weed exceeds 2 inches in height.		
³ Apply before weed exceeds 3 inches in height.		
⁴ Apply before weed exceeds 4 inches in height.		

TANK MIXTURES

It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture. Do not use a tank mix partner product if its label conflicts with this label.

Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** may be made as a sequential application in a planned post-emergence weed control program in corn following a pre-emergence herbicide. Consult the pre-emergence herbicide label for use restrictions, application information, rotational crop guidelines, and cautionary statements before making application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG**.

On Roundup® Ready corn, application of glyphosate may be made with **Mesotrione 31.25% + Rimsulfuron 7.5% WG** after weeds emerge but before they reach the maximum size listed on the glyphosate herbicide label.

On "LibertyLink" corn, application of glufosinate may be made with **Mesotrione 31.25% + Rimsulfuron 7.5% WG** after weeds emerge but before they reach the maximum size listed on the glufosinate herbicide label.

Refer to the **SPRAY ADJUVANTS** section for additional information on proper adjuvant selection.

Mesotrione 31.25% + Rimsulfuron 7.5% WG 4.0 oz./Acre with Glyphosate

Glyphosate may be tank mixed with post-emerge treatment of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** when made to corn hybrids that contain the "Roundup Ready" gene. Consult the **SPRAY ADJUVANTS** section for additional information on proper adjuvant selection.

When used in tank mixture with glyphosate, 4.0 oz. **Mesotrione 31.25% + Rimsulfuron 7.5% WG** will provide improved burndown and/or residual activity on the weeds listed in the table below:

Alfalfa, volunteer	Quackgrass
Canada thistle	Ryegrass, Italian
Chamomile, false	Sandbur (field, longspine)
Crabgrass	Shepherd's purse
Filaree, redstem	Signalgrass, broadleaf
Henbit	Stinkgrass
Johnsongrass, seedling	Waterhemp (smooth, tall)
Millet, wild proso	Wild buckwheat
Morningglory, ivyleaf	Wild oat
Mustard (birdsrape, black, wild)	Yellow nutsedge
Purslane, common	

Mesotrione 31.25% + Rimsulfuron 7.5% WG 4.0 oz./Acre with Glufosinate

When treatment is made to corn hybrids that contain the "LibertyLink" gene, **Mesotrione 31.25% + Rimsulfuron 7.5% WG** can be tank mixed with a glufosinate-containing herbicide. Consult your seed supplier to confirm the corn hybrid is "LibertyLink" before making application of any herbicide that contains glufosinate.

Tank Mixtures for Additional Control of Broadleaf and Grass Weeds

To provide added residual or burndown activity on emerged weeds, **Mesotrione 31.25% + Rimsulfuron 7.5% WG** may be tank mixed with other labeled post-emergence grass and broadleaf herbicides. Refer to the tank mix partner labeling for rate and soil-type restrictions. Ensure the tank mix product is labeled for the same timing, method of application, adjuvants, and use restrictions as **Mesotrione 31.25% + Rimsulfuron 7.5% WG** and other products used in the tank mixture.

EC formulation products, acetochlor or metolachlor herbicides can act like an adjuvant in certain combinations and therefore may increase the risk of crop injury. If these tank mixtures are used, the user should leave the crop oil concentrate (COC) out of the adjuvant mix.

Application of **Mesotrione 31.25% + Rimsulfuron 7.5% WG** may be made in tank mix with products that contain the same active ingredients, but special attention must be paid to adjuvant selection and/or application method. If any of

these tank mixtures are used the user should leave the urea ammonium nitrate (UAN) out of the mix. There is still risk of temporary crop injury with these mixtures. To further reduce the risk of crop injury, the user should also leave out the crop oil concentrate (COC), and replace it with a nonionic surfactant (NIS).

Control of weeds that have emerged may be reduced due to less than optimum adjuvant effect or weed coverage and there is still a risk of temporary crop injury with these mixtures.

The crop safety of all possible tank mixture combinations with **Mesotrione 31.25% + Rimsulfuron 7.5% WG** which may include physically compatible pesticides, fertilizers, adjuvants and/or additives has not been tested.

It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture. Do not use a tank mix partner product if its label conflicts with this label.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store product in original container only. Store in a cool, dry place.

Pesticide Disposal

Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Refer to the Net Contents section of this product's labeling for the applicable "Nonrefillable Container" or "Refillable Container" designation.

Nonrefillable Plastic and Metal Containers (Capacity Equal to or Less Than 50 Pounds): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, for Plastic Containers, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. For Metal Containers, offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Nonrefillable Plastic and Metal Containers (Capacity Greater Than 50 Pounds): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then, for Plastic Containers, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. For Metal Containers, offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

DO NOT USE CONTAINERS FOR THE STORAGE OF FOOD, FEED, OR DRINKING WATER!

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of this product, which are beyond the control of ROTAM AGROCHEMICAL COMPANY LIMITED or Seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold ROTAM AGROCHEMICAL COMPANY LIMITED and Seller harmless for any claims relating to such factors.

ROTAM AGROCHEMICAL COMPANY LIMITED warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent consistent with applicable law, this warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or ROTAM AGROCHEMICAL COMPANY LIMITED and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ROTAM AGROCHEMICAL COMPANY LIMITED MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law, in no event shall ROTAM AGROCHEMICAL COMPANY LIMITED or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ROTAM AGROCHEMICAL**

COMPANY LIMITED AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF ROTAM AGROCHEMICAL COMPANY LIMITED OR SELLER, THE REPLACEMENT OF THE PRODUCT.

ROTAM AGROCHEMICAL COMPANY LIMITED and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of ROTAM AGROCHEMICAL COMPANY LIMITED.

All trademarks are the property of their respective owners.

Decision Seq: 529233 Action Code: R310,NEW END-USE OR MANUFACTURING USE PRODUCT ... ?

FFS Start Date: 29-May-2017 Tentative Ind: No Start/Stop Clock FQPA Clock:

Due Date: 29-Dec-2017 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 29-May-2017 FFS Original Decision:

Negotiated Due Date: 90-Day Due Date: 28-Aug-2017

Registrant Response Due Date: Predecisional Due Date: 15-Dec-2017 Add to Bundle?

Current Status: PENDING (09-May-2017) Bundle ID:

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Bundle

75 Day Letters 45/90 Day Screen Primary Decisions Decision Milestone

FFS Negotiated Due Dates 18 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:1003248	Pahel, Lisa	... 83100-LT	29-Dec-2017	PENDING
New End Use Product				

Pahel, Lisa

From: Pahel, Lisa
Sent: Wednesday, November 08, 2017 11:24 AM
To: 'Anna Armstrong'
Cc: Kt Woodall
Subject: RE: Label comments for 83100-LT

Thank you Anna. We are okay with air blast section remaining on this label.

Best,
Lisa

From: Anna Armstrong [mailto:Anna@wagnerreg.com]
Sent: Wednesday, November 08, 2017 10:55 AM
To: Pahel, Lisa <Pahel.Lisa@epa.gov>
Cc: Kt Woodall <ktwoodall@wagnerreg.com>; Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: Label comments for 83100-LT

Hi Lisa,
Please find attached the revised draft label for the referenced product with changes incorporated (clean and highlighted copies). I believe I have captured all of your comments and the comments specific to the SU Interim Decision for Rimsulfuron. But, if not, please let me know.

Page 6: Regarding the EPA comment for the removal of the Air Blast Field Crop Sprayers section - This application method is registered for use on the EPA Reg. 352-837 label which has the same use information and active ingredient concentrations as this proposed product. Therefore, it is respectfully requested to retain this application method.

Thanks very much for your efforts on this review.

Take care,
Anna

From: Pahel, Lisa [mailto:Pahel.Lisa@epa.gov]
Sent: Thursday, November 2, 2017 8:49 AM
To: Anna Armstrong <Anna@wagnerreg.com>
Subject: Label comments for 83100-LT

Hi Anna,

Please see the attached comments for 83100-LT, and let me know if you have any questions.

Best,
Lisa

Lisa Pahel
Environmental Protection Specialist
Fungicide and Herbicide Branch
Registration Division
Office of Pesticide Programs

Pahel, Lisa

From: Anna Armstrong <Anna@wagnerreg.com>
Sent: Wednesday, November 08, 2017 10:55 AM
To: Pahel, Lisa
Cc: Kt Woodall; Anna Armstrong
Subject: RE: Label comments for 83100-LT
Attachments: 83100-LT EK 11-2-17.pdf; 83100-LT.20170505.V2 highlighted.pdf; 83100-LT.20170505.V2.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Lisa,
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Anna

From: Pahel, Lisa [mailto:Pahel.Lisa@epa.gov]
Sent: Thursday, November 2, 2017 8:49 AM
To: Anna Armstrong <Anna@wagnerreg.com>
Subject: Label comments for 83100-LT

Hi Anna,

Please see the attached comments for 83100-LT, and let me know if you have any questions.

Best,
Lisa

Lisa Pahel
Environmental Protection Specialist
Fungicide and Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0459



Completion of 21-Day Content Screen

PM- 24

EPA Reg. # (File Symbol) 83100-LT

Decision # D

Data package delivered to
you on 5/25.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

Memorandum

E-SUBMISSION

Date: 5 / 12 / 17

To: PM 24, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 10, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.
ROTAM AGROCHEMICAL COMPANY, LTD.
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 05-MAY-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**
Rotam Agrochemical Company Ltd.
c/o Wagner Regulatory Associates
P.O. Box 640, 7217 Lancaster Pike, Suite A
Hockessin, DE 19707
2. **Regulatory Action In Support Of Which This Package Is Submitted**
Application for Registration
Mesotrione 31.25% + Rimsulfuron 7.5% WG
3. **Transmittal Date**
May 5th, 2017
4. **List of Submitted Studies**

50258101	Mesotrione 31.25% + Rimsulfuron 7.5% WG Product Identity and Composition, Description of Materials, Description of Formulation Process, Preliminary Analysis and Certified Limits, OPPTS: 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750
50258102	Study On The Method Validation Of Rimsulfuron 7.5% + Mesotrione 31.25% Water Dispersible Granules, Study No. 1964, OPPTS: 830.1800
50258103	Study On The Physico-Chemical Properties Of Rimsulfuron 7.5% + Mesotrione 31.25% Water Dispersible Granules, Study No. 1965, OPPTS: 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6316, 830.6317, 830.6319, 830.6320, 830.7000, 830.7300, 830.7520
50258104	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Oral Toxicity Study (Up-and-Down Procedure) in female Wistar rats , Study No. 17001, OPPTS: 870.1100
50258105	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Dermal Toxicity Study in Wistar Rats , Study No. 17002, OPPTS: 870.1200
50258106	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Inhalation Toxicity Study in Wistar Rats, Study No. 17006, OPPTS: 870.1300
50258107	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Eye Irritation / Corrosion Study in New Zealand White Rabbits, Study No. 17004, OPPTS: 870.2400
50258108	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Dermal Irritation / Corrosion Study in New Zealand White Rabbits, Study No. 17003, OPPTS: 870.2500
50258109	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs, Study No. 17005, OPPTS: 870.2600
50258110	Mesotrione 31.25% + Rimsulfuron 7.5% WG - Product Chemistry - Group B: Request for Waiver for Certain Physical / Chemical Properties Data, OPPTS: 830.6313, 830.6315, 830.6321, 830.7050, 830.7100, 830.7200, 830.7220, 830.7370, 830.7550, 830.7560, 830.7570, 830.7840, 830.7860, 830.7950

Company Official:

Anna Armstrong
Authorized Agent


Signature

Company Name: Rotam Agrochemical Company Ltd.

Company Contact:

Anna Armstrong
Authorized Agent

(302) 510-0039
Phone

Submitted Electronically

May 5th, 2017

Document Processing Desk (REGFEE)
ATTN: Erik Kraft (PM 24)
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202



Wagner Regulatory Associates, Inc.
P.O. Box 640
7227 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Subject: Application to Register a New End-Use Product
"Mesotrione 31.25% + Rimsulfuron 7.5% WG" - (PRIA R310)

Dear Mr. Kraft,

Wagner Regulatory Associates, Inc., as agent for Rotam Agrochemical Co., Ltd., is requesting registration of the above referenced product containing the currently registered active ingredients Mesotrione (PC code 122990) and Rimsulfuron (PC code 129009). In support of this request, the following documents and studies are being submitted electronically via the EPA CDX PSP portal:

- Letter from Rotam Agrochemical Co., Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35), internal and public versions
- Data Transmittal Document
- Formulators Exemption (8570-27)
- Data as outlined in the Transmittal Document
- Draft Label
- Certification with Respect to Label Integrity
- Receipt confirming payment of fee for PRIA R310 - \$5,301.

Thank you in advance for your efforts in reviewing this submission. Please do not hesitate to contact me by email at anna@wagnerreg.com or by phone at 302-510-0039 should you have any questions.

Respectfully submitted,

Anna Armstrong
Agent for Rotam Agrochemical Co., Ltd.

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707	EPA File Symbol/Registration Number 83100-XX
	Product Name Mesotrione 31.25% + Rimsulfuron 7.5% WG
	Date of Confidential Statement of Formula (EPA Form 8570-4) 05/05/2017

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Mesotrione + Rimsulfuron

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Mesotrione	[REDACTED]	[REDACTED]
Rimsulfuron	[REDACTED]	[REDACTED]
Signature 	Name and Title Anna Armstring, Agent	Date 05/05/2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Agrochemical Company Ltd., c/o WRA, Inc., P.O. Box 840, 7217 Lancaster Pike, Ste A, Hockessin, DE 19707	EPA Registration Number/File Symbol 83100-XX
Active Ingredient(s) and/or representative test compound(s) Mesotrione + Rimsulfuron	Date May 5, 2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Crops	Product Name Mesotrione 31.25% + Rimsulfuron 7.5% WG

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 05/05/2017	Typed or Printed Name and Title Anna Armstrong, Agent
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 5 th , 2017		EPA Reg. No. / File Symbol: 83100-XX	Page 1 of 2
Applicant's/Registrant's Name and Address: Rotam Agrochemical Co., Ltd. 26/F, E-Trade Plaza 24 Lee Chung Street Chai Wan, Hong Kong		Product: Mesotrione 31.25% + Rimsulfuron 7.5% WG	
Ingredient: Mesotrione + Rimsulfuron			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600	Product identity, composition/Description of materials Used to Produce the Product	50258101	Rotam Agrochemical Co., Ltd.	Own	
830.1650	Description of Formulation Process	50258101	Rotam Agrochemical Co., Ltd.	Own	
830.1670	Discussion of Formation of Impurities	50258101	Rotam Agrochemical Co., Ltd.	Own	
830.1700	Preliminary Analysis	50258101	Rotam Agrochemical Co., Ltd.	Own	
830.1750	Certification of Limits	50258101	Rotam Agrochemical Co., Ltd.	Own	
830.1800	Enforcement Analytical Method	50258102	Rotam Agrochemical Co., Ltd.	Own	
830.6302	Color	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6303	Physical State	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6304	Odor	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures	50258103 50258110	Rotam Agrochemical Co., Ltd.	Own	
830.6314	Oxidation/Reduction	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6315	Flammability	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.6316	Explosibility	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6317	Storage Stability	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6319	Miscibility	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6320	Corrosion Characteristics	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.6321	Dielectric Voltage Breakdown	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.7000	pH	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.7050	UV/Visible Absorption	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.7100	Viscosity	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.7200, 830.7220	Melting Point/Boiling Point	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.7300	Relative Density	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.7370	Dissociation Constant	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.7520	Particle Size Distribution	50258103	Rotam Agrochemical Co., Ltd.	Own	
830.7550, 830.7560, 830.7570	Octanol Water Partition Coefficient	50258110	Rotam Agrochemical Co., Ltd.	Own	
830.7840, 830.7860	Solubility	50258110	Rotam Agrochemical Co., Ltd.	Own	

Signature 	Name and Title Anna Armstrong, Agent for Rotam Agrochemical Co., Ltd.	Date May 5 th , 2017
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DATA MATRIX

Date: May 5th, 2017

EPA Reg. No. / File Symbol: 83100-XX

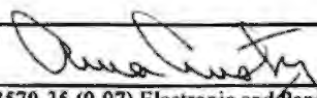
Page 2 of 2

Applicant's/Registrant's Name and Address: Rotam Agrochemical Co., Ltd.
26/F, E-Trade Plaza
24 Lee Chung Street
Chai Wan, Hong Kong

Product:
Mesotrione 31.25% + Rimsulfuron 7.5% WG

Ingredient: Mesotrione + Rimsulfuron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor Pressure	50258110	Rotam Agrochemical Co., Ltd.	Own	
870.1100	Acute Oral Toxicity	50258104	Rotam Agrochemical Co., Ltd.	Own	
870.1200	Acute Dermal Toxicity	50258105	Rotam Agrochemical Co., Ltd.	Own	
870.1300	Acute Inhalation Toxicity	50258106	Rotam Agrochemical Co., Ltd.	Own	
870.2400	Primary Eye Irritation	50258107	Rotam Agrochemical Co., Ltd.	Own	
870.2500	Primary Dermal Irritation	50258108	Rotam Agrochemical Co., Ltd.	Own	
870.2600	Dermal Sensitization	50258109	Rotam Agrochemical Co., Ltd.	Own	

Signature 	Name and Title Anna Armstrong, Agent for Rotam Agrochemical Co., Ltd.	Date May 5 th , 2017
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DP Barcode No.: D440413
PC Code: 129009,122990
Food Use: Yes

Symbol No.: 83100-LT Decision No.: 529233
Company Name: Rotam Agrochemical Company, Limited
Action Code: R 310 Product Name: Mesotrione 31.25%+Rimsulfuron 7.5% WG

4. All inert ingredients have been screened by IIAB and are approved for the proposed labeled uses.

5. Confidential Statement of Formula:

☒ Basic - Dated: 05 May 2017 Resubmitted Dated:
☐ Alternate - Dated: Resubmitted Dated:

Alternate CSF complies with 40 CFR 152.43
☐ Yes ☐ No ☒ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF concurs with product label (PR Notice 91-2).
☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)
☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA
Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA
Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?
☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
☐ Yes; ☐ No; ☒ NA; if not, explain below

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below

DP Barcode No.: D440413

Line Symbol No.: 83100-LT

Decision No.: 529233

PC Code: 129009,122990

Company Name: Rotam Agrochemical Company, Limited

Food Use: Yes

Action Code: R 310 Product Name: Mesotrione 31.25%+Rimsulfuron 7.5% WG

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	502581-01
830.1600	Description of materials used to produce the product		X		A	502581-01
830.1650	Description of formulation process		X		A	502581-01
830.1670	Discussion on the formation of impurities		X		A	
830.1700	Preliminary analysis			X	N/A	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	see basic csf 5/5/17
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	502581-02

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP Barcode No.: D440413
PC Code: 129009,122990
Food Use: Yes

Symbol No.: 83100-LT Decision No.: 529233
Company Name: Rotam Agrochemical Company, Limited
Action Code: R 310 Product Name: Mesotrione 31.25%+Rimsulfuron 7.5% WG

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Product is a pale brown odorless solid at 25°C.	A	502581-03
830.6314	Oxidation/Reduction	Product is compatible when mixed with water, 10% monoammonium phosphate, Zn powder, 10% potassium permanganate and kerosene.	A	502581-03
830.6315	Flammability	The granule train did not ignite after hot flame applied for 2 minutes.	A	502581-03
830.6316	Explodability	This product is not sensitive when exposed to mechanical shock, friction, or thermal exposure.	A	502581-03
830.6317	Storage stability	Active ingredient content remained relatively unchanged after 14-days storage at 54°C.	A	502581-03
830.6320	Corrosion Characteristics	The test container's appearance was remained unchanged after 14-days storage at 54°C.		
830.7000	pH	4.62	A	502581-03
830.7100	Viscosity	Product is a solid.	N/A	
830.7300	Density (units)	0.72 g/mL (pour) 0.78 g/mL (tap)	A	502581-03

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress;
U = Upgradeable.

DP Barcode No.: D440413

Product Symbol No.: 83100-LT

Decision No.: 529233

PC Code: 129009,122990

Company Name: Rotam Agrochemical Company, Limited

Food Use: Yes

Action Code: R 310 Product Name: Mesotrione 31.25%+Rimsulfuron 7.5% WG

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 352-837) from Product chemistry view point

- ☒ Similar
- ☐ Not similar, give reasons
- ☐ Identical
- ☐ Not identical
- ☐ Not applicable

B. Confidential Statement of formula

1. Basic CSF (dated 05 May 2017)

- ☒ Acceptable
- ☐ Not Acceptable
- ☐ Not Applicable

If not acceptable provide the reasons

2. Alternate CSF

- ☐ Acceptable
- ☐ Not Acceptable
- ☒ Not Applicable

If not acceptable give reasons

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
- ☐ Not required
- ☐ Data cited

D. Group B Product chemistry data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
- ☐ Not required
- ☐ Data cited

E. Product Label/Draft Label

Recommendations – Yes ☐; No ☒

If yes, give recommendations below:

Note: Please add additional remarks if necessary for each section



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D440413 FILE SYMBOL No.: 83100-LT (screen) DECISION No.: 529233
PC Codes: 129009,122990 Company Name: Rotam Agrochemical Company, Limited
FOOD Use: Yes ACTION CODE: R 310 PRODUCT NAME: Mesotrione 31.25%+Rimsulfuron
7.5% WG

DATE OUT: August 17, 2017

SUBJECT: Completeness Check Screen for an End-Use Product

Product Name: Mesotrione 31.25%+Rimsulfuron 7.5% WG

FROM: Bruce Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

Bruce Kitchens
8/17/17

TO: RM #24, Erik Kraft/Lisa Pahel
Fungicide and Herbicide Branch
Registration Division (7505P)

Company Name: Rotam Agrochemical Company, Limited

Active Ingredients: Rimsulfuron (7.5% a.i.)
Mesotrione (31.25% a.i.)

MRID Nos.: 502581-01, 502581-02, 502581-03 & 502581-10

CONCLUSIONS:

Deficiencies: No
(If there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted.

Group B: All required data submitted.

CSF: Basic CSF dated 05 May 2017

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and return to me the corrected deficiencies in response to 10-day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

October 26, 2017

MEMORANDUM:

Subject: Pesticide Product Name: MESOTRIONE 31.25% + RIMSULFURON 7.5% WG
EPA File Symbol: 83100-LT
DP Barcode: DP 440414
Decision No.: 529233
Action Code: R310
Submission: #1003248
E-Sub: 19480
PC Codes: 129009 (Rimsulfuron: 7.5%)
122990 (Mesotrione: 31.25%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
Oct-26-2017

Through: P.V. Shah, Ph.D., Branch Chief
CITAB
Registration Division (7505P)

P.V. Shah *10/26/2017*

To: Lisa Pahel / Eric Kraft, RM 24
Fungicide-Herbicide Branch
Registration Division (7505P)

Registrant: ROTAM AGROCHEMICAL COMPANY, LTD.

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
122990 Mesotrione.....	31.25%
129009 Rimsulfuron: N-((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)-3-(ethylsulfonyl)-2-pyridinesulfonamide.....	7.50%
OTHER INGREDIENTS.....	61.25%
TOTAL	100.00%

ACTION REQUESTED: "Rotam Agrochemical Co. Ltd. has submitted an application to register a new end-use product containing mesotrione and rimsulfuron (R310). They are claiming similarity to EPA Reg. No. 352-837. Please review the submitted acute toxicity data to determine whether the application is acceptable from an acute tox standpoint. The proposed Basic CSF is enclosed in this package; the rest of the submission can be found in Documentum under e-submission #19480..."

BACKGROUND: The registrant is claiming similarity to EPA Reg. No. 352-837, but has submitted 6 acute toxicity studies (MRIDs 502581-04 through -09) to support 83100-LT.

COMMENTS AND RECOMMENDATIONS:

1. CITAB has reviewed the six acute toxicity studies in MRIDs 50258104 through 50258109. Each of the six studies has been classified as acceptable.
2. Based on the results from the six acute toxicity studies, the following is the acute toxicity profile for 83100-LT:

Oral LD ₅₀ (rat)	Toxicity Category III	MRID 50258104	Acceptable
Dermal LD ₅₀ (rat)	Toxicity Category III	MRID 50258105	Acceptable
Inhalation LC ₅₀ (rat)	Toxicity Category IV	MRID 50258106	Acceptable
Eye Irritation (rabbit)	Toxicity Category IV	MRID 50258107	Acceptable
Dermal Irritation (rabbit)	Toxicity Category III*	MRID 50258108	Acceptable
Dermal sensitization (g. pig)	Negative	MRID 50258109	Acceptable

*Since MRID 50258108 indicates the test material was applied over an area of 6 cm x 6 cm (=36 cm²) instead of 6 cm² this formulation has been assigned to toxicity category III rather than IV.

3. Based on the acute toxicity profile given above, as well as information from the proposed label and CSF, the following is the precautionary and first aid labeling for 83100-LT, based on information from the proposed label, CSF, output from the Label Review System and the current Label Review Manual:

PRODUCT ID #: 083100-00057

PRODUCT NAME: MESOTRIONE 31.25% + RIMSULFURON 7.5% WG

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber). Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

4. The precautionary and first aid labeling as proposed by the registrant is acceptable, except the "IF IN EYES" first aid statement must follow the "IF ON SKIN OR CLOTHING" and "IF SWALLOWED" (the formulation is in toxicity category III for dermal toxicity/irritation and by the oral exposure route, while it is in category IV for eye and inhalation exposure).
5. The acute toxicity data requirements for the registration of 83100-LT have been satisfied by MRIDs 502581-04 through -09.
6. The CSF and chemistry data for 83100-LT must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

Reviewer: Byron T. Backus, Ph.D.

Date: October 26, 2017

Risk Manager (EPA): 24

The following is the Acute Toxicity Data Evaluation Record (DER) for the acute toxicity studies (MRIDs 502581-04 through -09) submitted to support the registration of EPA File Symbol 83100-LT (Mesotrione 31.25% + Rimsulfuron 7.5% WG).

1. DP BARCODE: 440414				
2. PC CODES: 122990 (Mesotrione: 31.25%); 129009 (Rimsulfuron: 7.5%)				
3. CURRENT DATE: October 26, 2017				
4. TEST MATERIAL: From p. 14 of MRID 50258104: Rimsulfuron 7.5% + Mesotrione 31.25% WG; Batch No. 20161217001, containing 31.69% Mesotrione and 7.62% Rimsulfuron; described as pale brown granules. From p. 15 of MRID 50258107 the pH of a 1% v/v aqueous solution was 4.8				
Study	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity (Up and down procedure) / rat / Palamur Biosciences Private Limited (PBS), Mahabubnagar – 509382, Telangana State, India / Study No. 17001 / 22 March, 2017 / OCSPP 870.1100; OECD 425	50258104	Five fasted female Wistar rats were dosed (oral gavage) with 2000 mg Rimsulfuron 7.5% + Mesotrione 31.25%/kg in distilled water (concentration: 200 mg/mL). The administered dose volume was 10 mL/kg. Results: There was no mortality and there were no signs of toxicity. All rats gained weight days 0-7 and 7-14. There were no gross abnormalities at necropsy. Oral LD ₅₀ > 2000 mg/kg.	III	A
Acute dermal toxicity / rat / Palamur Biosciences Private Limited (PBS), Mahabubnagar – 509382, Telangana State, India / Study No. 17002 / 22 March, 2017 / OCSPP 870.1200; OECD 402	50258105	5M and 5F Wistar rats were each dermally exposed for 24 hours to 2000 mg/kg of test material which had been moistened with a minimum amount of water to form a paste. Application was to an area of ~10% of the total body surface which was covered with a gauze dressing bandaged with non-irritating tape during exposure. After 24 hrs dressing were removed and the dose sites were cleansed. Results: All rats survived. There were no signs of toxicity and there was no dermal irritation. All rats gained weight days 0-7 and 7-14. There were no gross abnormalities at necropsy. Dermal LD ₅₀ > 2000 mg/kg.	III	A

Acute inhalation toxicity / rat / Palamur Biosciences Private Limited (PBS), Mahabubnagar – 509382, Telangana State, India / Study No. 17006 / 22 March, 2017/ OCSPP 870.1300; OECD 403	50258106	A group of 5M & 5F Wistar rats was exposed (nose only) for 4 hours to a mean concentration of 2.876 mg Rimsulfuron 7.5% + Mesotrione 31.25%/L (nominal: 10.76 mg/L). The MMAD was 2.09 μ m and the mean GSD was 2.57. There was a 14-day observation period following exposure. Results: There was no mortality. There were no signs of toxicity during or following exposure. All rats gained weight days 0-7 and 7-14. There were no gross abnormalities at necropsy. Inhalation LC ₅₀ > 2.876 mg/L.	IV	A
Primary eye irritation / rabbit / Palamur Biosciences Private Limited (PBS), Mahabubnagar – 509382, Telangana State, India / Study No. 17004 / 22 March, 2017 / OCSPP 870.2400; OECD 405	50258107	The test material (Rimsulfuron 7.5% + Mesotrione 31.25%) was made into a fine powder and 100 mg was instilled into the left eye of each of 3 NZW rabbits. The eyes were treated with an ocular anesthetic prior to this instillation. Results: There was no corneal opacity, iritis or conjunctival irritation. All eyes scored zero at 1, 24, 48 and 72 hrs.	IV	A
Primary dermal irritation / rabbit / Palamur Biosciences Private Limited (PBS), Mahabubnagar – 509382, Telangana State, India / Study No. 17003 / 22 March, 2017 / OCSPP 870.2500; OECD 404	50258108	0.5 g Rimsulfuron 7.5% + Mesotrione 31.25% was applied to an intact dose site on each of 3 NZW rabbits. According to the report (p. 8) “A dose of 0.5 g of test item...was applied to the skin, over an area of approximately 6 x 6 cm [= 36 cm ²] clipped of hair on side of rabbits.” [The 870.2500 Guidelines specify application to 6 cm²]. The test material was mixed with a “minimum quantity of water.” Each dose site was covered with a gauze patch during the 4-hr exposure. Sites were scored (Draize) at 30-60 minutes, 24, 48 and 72 hrs after patch removal. At 1, 24, 48 and 72 hrs all scores were zero. PDII = 0.00. Since report indicates test material was applied over 36 cm ² (rather than 6 cm ²) test material is assigned to toxicity category III (not IV) for dermal irritation.	III	A

<p>Dermal sensitization: Magnusson Kligman Maximization Test / Guinea pig / Palamur Biosciences Private Limited (PBS), Mahabubnagar – 509382, Telangana State, India / Study No. 17005 / 22 March, 2017/ OCSPP 870.2600; OECD 406</p>	<p>50258109</p>	<p>There were 10 Dunkin Hartley albino guinea pigs in the treatment (induced) group and 5 in the control (non-induced) group. Concentrations used were based on pretesting. On day 0 each guinea pig in the treatment group received 3 pairs of 0.1 mL intradermal injections 1):1:1 Freund's Complete Adjuvant : Physiological Saline; 2): 0.1 mL 10% test item in propylene glycol; and 3) 0.1 mL of a 1:1 mixture of 1) and 2). Guinea pigs in the control group were similarly treated but without the test material. On day 7 treatment animals were dermally exposed on the right shoulder (for 48 hrs) to a 2 cm x 4 cm piece of filter paper "fully loaded with test item (100% of test item, 200 mg) to saturation level by moistened with distilled water." Controls were exposed to distilled water. On day 21 3 cm x 3 cm filter papers "fully loaded with the test item (75% of test item, 150 mg) to saturation level by moistened with distilled water" were applied to the left flank of all (treatment and control) guinea pigs with 24-hr occlusive exposure. Results: All scores were zero at 24 and 48 hrs following the end of challenge exposure. The report includes a positive control (2-Mercapto-benzothiazole) study conducted October-November 2016 in which a positive response was observed in 50% of the guinea pigs.</p>	<p>Negative</p>	<p>A</p>
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n.d. = not determined; Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap

21-Day Screen Completed by
Contractor

Waiting for Data
5/17

21-Day Expires on 5-26-17

Jacket # 83100-LT

MRID# 502581

Content Screen: Recommend to ☒ **Pass** / Fail

11-3 Review: ☒ **Pass** / Fail / NA

Overall Status: Recommend to ☒ **Pass** / Fail

Transfer This Jacket to:

MEREDITH LAWS

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 5-5-17 September 2012

Experts In-Processing Signature: B.B. Date 5-10-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>83100-LT</u>		EPA Receipt Date: <u>5-5-17</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			<input checked="" type="checkbox"/>		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes <input checked="" type="checkbox"/>	no <input type="checkbox"/>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent			<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes <input type="checkbox"/>	no <input type="checkbox"/>			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			<input checked="" type="checkbox"/>		
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
	a) Selective Method (Fee category experts use)	yes <input checked="" type="checkbox"/>	no <input type="checkbox"/>			
	b) Cite-All (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>			
	c) Applicant owns all data (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>			
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			<input checked="" type="checkbox"/>		
7	Is the data package consistent with PR Notice 86-5			<input checked="" type="checkbox"/>		
8	Notice of Filing included with petitions					<input checked="" type="checkbox"/>

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Documentation: Pass / Fail
 - Request forms are complete

* Zvents: Pass / Fail
 - Zvents approval for food use under Pre-Harvest Application
 - Sniffer listed on the CSF

* PRN II-3: Pass / Fail
 MRZD: 502581

JA 5-16-17

* Overall Status: Pass / Fail

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis	✓					
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explosibility	✓					
830.6317	Storage stability	✓					
830.6319	Miscibility	✓					
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage	✓					
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	✓			
870.1200	Acute Dermal (LD50)	✓			
870.1300	Acute Inhalation (LC50)	✓			
870.2400	Acute Eye Irritation	✓			
870.2500	Acute Dermal Irritation				
870.2600	Dermal Sensitization	✓			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					PLA
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					"
810.3300	Treatments to Control Pests of Humans and Pets					"
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					"
810.3500	Premises Treatments					"
810.3600	Structural Treatments					"
810.3800	Methods for Efficacy Testing of Termite Baits					"



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 9, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-529233
EPA File Symbol or Registration Number: 83100-LT
Product Name: Mesotrione 31.25% + Rimsulfuron 7.5% WG
EPA Receipt Date: 05-May-2017
EPA Company Number: 83100
Company Name: ROTAM AGROCHEMICAL COMPANY, LTD.

MS. ANNA AMSTRONG
WAGNER REGULATORY ASSOCIATES, INC.
ROTAM AGROCHEMICAL COMPANY, LTD.
PO Box 640, 7217 LANCASTER PIKE, SUITE A
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S); INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS; REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY; INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;; PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY; CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in black ink, appearing to be "Jill".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{1003248D~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 22

Receipt No.

S-

1003248

EPA File Symbol/Reg. No.

83100-LT

Pin-Punch Date:

5/5/2017

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R30

Amount Due: \$ 5301

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: ψ. GARNE

Date: 5/9/17

Remarks:

Need to re-code if these 2 actives have never been combined together. (R314)

DOCUMENTUM

From: notification@pay.gov
To: Anna Armstrong
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Friday, May 5, 2017 9:54:27 AM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2629DEOJ
Agency Tracking ID: 75238953032
Transaction Type: Sale
Transaction Date: 05/05/2017 09:54:20 AM EDT

Account Holder Name: Cheryl R. Wagner

Transaction Amount: \$5,301.00
Card Type: AmericanExpress
Card Number: *****2008

Registration Number:
Company Name: Rotam Agrochemical
Company Number: 83100
Action Code: R310

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

DOCUMENTUM



United States
Environmental Protection Agency
Washington, DC 20460



Registration



Amendment



Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83100-XX	2. EPA Product Manager Erik Kraft	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Agrochemical Co. Ltd. / Mesotrione 31.25% + Rimsulfuron 7.5% WG	PM# 24	
5. Name and Address of Applicant (Include Zip Code) Rotam Agrochemical Company Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-837 Product Name: DuPont Realm Q Herbicide	

Section - II

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input checked="" type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

PRIA R310 - New End Use Product Registration

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 20 oz.; 80 oz.; 20 oz. x12; 80 oz. x12		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ adhesive backed label _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Anna Armstrong		Title Agent for Rotam Agrochemical Company Ltd.		Telephone No. (Include Area Code) (302) 510-0039 (anna@wagnerreg.com)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Rotam Agrochemical Company Ltd.			
4. Typed Name Anna Armstrong		5. Date May 5 th , 2017			

Submitted Electronically

May 5th, 2017

Document Processing Desk (REGFEE)
ATTN: Erik Kraft (PM 24)
Registration Division (7505P)
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202



WRA

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

**Subject: Application to Register a New End-Use Product
"Mesotrione 31.25% + Rimsulfuron 7.5% WG" - (PRIA R310)**

Dear Mr. Kraft,

Wagner Regulatory Associates, Inc., as agent for Rotam Agrochemical Co., Ltd., is requesting registration of the above referenced product containing the currently registered active ingredients Mesotrione (PC code 122990) and Rimsulfuron (PC code 129009). In support of this request, the following documents and studies are being submitted electronically via the EPA CDX PSP portal:

- Letter from Rotam Agrochemical Co., Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35), internal and public versions
- Data Transmittal Document
- Formulators Exemption (8570-27)
- Data as outlined in the Transmittal Document
- Draft Label
- Certification with Respect to Label Integrity
- Receipt confirming payment of fee for PRIA R310 - \$5,301.

Thank you in advance for your efforts in reviewing this submission. Please do not hesitate to contact me by email at anna@wagnerreg.com or by phone at 302-510-0039 should you have any questions.

Respectfully submitted,

Anna Armstrong
Agent for Rotam Agrochemical Co., Ltd.

Enclosures

DOCUMENTUM

DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**
Rotam Agrochemical Company Ltd.
c/o Wagner Regulatory Associates
P.O. Box 640, 7217 Lancaster Pike, Suite A
Hockessin, DE 19707
2. **Regulatory Action In Support Of Which This Package Is Submitted**
Application for Registration
Mesotrione 31.25% + Rimsulfuron 7.5% WG
3. **Transmittal Date**
May 5th, 2017
4. **List of Submitted Studies**

50258101	Mesotrione 31.25% + Rimsulfuron 7.5% WG Product Identity and Composition, Description of Materials, Description of Formulation Process, Preliminary Analysis and Certified Limits, OPPTS: 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750
50258102	Study On The Method Validation Of Rimsulfuron 7.5% + Mesotrione 31.25% Water Dispersible Granules, Study No. 1964, OPPTS: 830.1800
50258103	Study On The Physico-Chemical Properties Of Rimsulfuron 7.5% + Mesotrione 31.25% Water Dispersible Granules, Study No. 1965, OPPTS: 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6316, 830.6317, 830.6319, 830.6320, 830.7000, 830.7300, 830.7520
50258104	Rimsulfuron 7.5 % + Mesotrione 31.25 %o WG: Acute Oral Toxicity Study (Up-and-Down Procedure) in female Wistar rats , Study No. 17001, OPPTS: 870.1100
50258105	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Dermal Toxicity Study in Wistar Rats , Study No. 17002, OPPTS: 870.1200
50258106	Rimsulfuron 7.5 % + Mesotrione 31.25 %o WG: Acute Inhalation Toxicity Study in Wistar Rats, Study No. 17006, OPPTS: 870.1300
50258107	Rimsulfuron 7.5 % + Mesotrione 31.25 % WG: Acute Eye Irritation / Corrosion Study in New Zealand White Rabbits, Study No. 17004, OPPTS: 870.2400
50258108	Rimsulfuron 7.5 %o + Mesotrione 31.25 % WG: Acute Dermal Irritation / Corrosion Study in New Zealand White Rabbits, Study No. 17003, OPPTS: 870.2500
50258109	Rimsulfuron 7.5 % + Mesotrione 31.25 %o WG: Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs, Study No. 17005, OPPTS: 870.2600
50258110	Mesotrione 31.25% + Rimsulfuron 7.5% WG - Product Chemistry – Group B: Request for Waiver for Certain Physical / Chemical Properties Data, OPPTS: 830.6313, 830.6315, 830.6321, 830.7050, 830.7100, 830.7200, 830.7220, 830.7370, 830.7550, 830.7560, 830.7570, 830.7840, 830.7860, 830.7950

Company Official:

Anna Armstrong
Authorized Agent


Signature

Company Name: Rotam Agrochemical Company Ltd.

Company Contact:

Anna Armstrong
Authorized Agent

(302) 510-0039
Phone

DOCUMENTUM

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